

K123094 ORTHODONTIC CERAMIC BRACKETSDec 13, 2012
72 days to decisionK123094 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k123094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Oct 2, 2012
Decision date	Dec 13, 2012
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tomy, Inc.
Location	Bradenton, FL, US
Contact	CAROLYN PRIMUS
510(k) history	4 submissions · 4 cleared · 2012-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123094/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026